(95%). From their past experience, 21% of them mentioned that they seldom get their drugs labeled whereas 14% of the total respondents were not sure whether they get their drugs labeled or not. In this study, gender, age, and level of education showed significant associations with most responses ($P < 0.05$). **CONCLUSIONS:** General public in Malaysia are aware about the importance of drug labeling and about one fifth of the population surveyed rarely receive their medicines labeled appropriately. Therefore, decision makers have to strictly enforce the existing drug labeling requirements for dispensed medications.

PIH38

STUDY OF THE DEGREE OF SATISFACTION OF PATIENTS WITH URINARY DISORDERS, EVOCATIVE OF BPH

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OBJECTIVES: Patient satisfaction, in response to a treatment, is an element of the medical service rendered. We quantified the satisfaction of patients treated medically for urinary disorders. **METHODS:** A pragmatic cohort (France, Italy, and Portugal) of 420 patients treated with Serenoa Repens, α-blocker or 5 α-reductase inhibitor, was followed-up for 6 months. **RESULTS:** A total of 175 patients were evaluated. Satisfaction was expressed as the differential between the expectation of the patients recorded before the start of treatment and the status declared at 6 months. In addition a binary (yes/no) question regarding general satisfaction was used as the primary evaluation criterion. We observed positive satisfaction in 61.7% of subjects in terms of the "effort or force needed to start urinating", 51.1% for the "size and force of the stream of urine", 54.35% for "sensation of not emptying the bladder after urinating", 52.38% for "interrupting the flow", and 50% for the "need to urinate". We observed negative satisfaction in 68.18% of subjects with respect to the progression of "getting up in the night to urinate". At 6 months, the response to the general satisfaction question confirms these initial results—indeed, nearly 98% of subjects were satisfied with the treatment of their BPH. We did not see any significant difference between the 3 treatment groups. **CONCLUSIONS:** The individualised expectation of the patient will undoubtedly be one of the major preoccupations of the next few decades. Medical treatment for BPH is accompanied by a satisfaction that is compatible with long term compliance with the treatment by the patient.

PIH39

PATIENTS WITH URINARY DISORDERS, EVOCATIVE OF BPH WHAT ARE THEIR EXPECTATIONS?

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OBJECTIVES: The individualised expectations of the patient will undoubtedly be one of the major preoccupations in the next few decades to guarantee optimal treatment through compliance. **METHODS:** A pragmatic, European cohort (France, Italy, and Portugal) of 420 patients presenting with urinary disorders, evocative of BPH, was followed-up over 6 months. a questionnaire regarding expectations was handed out at the first consultation. **RESULTS:** A total of 317 patients were evaluated. The symptoms that 30.7% of patients wished to see improved with the highest priority were "getting up in the night to urinate", then for slightly less than 20%, "sensation of not emptying the bladder after urinating". Amongst the symptoms that patients were the least concerned about were "the effort or force needed to start urinating" for 23% of responders, then "the interruption of the flow of urine" for 16% and the "size and force of the stream of urine". "Getting up in the night" was the principal complaint in all 3 countries (39% in France, 26 and 25% in Italy and Portugal), similarly "the effort or force needed to start urinating" is the symptom that preoccupies the patients the least in France and Italy, the "size and force of the stream of urine" preoccupies the Portuguese the least. Nearly 90% of the Italians claimed that they would only be satisfied if they never had to get up in the night again, (35% for the French, 50% for the Portuguese). Overall, 60% of the subjects questioned said that they would be satisfied if they were "markedly" improved. **CONCLUSIONS:** The expectation of patients in the treatment of BPH is very important, and undoubtedly difficult to satisfy entirely. These results are probably due to the fact that our population was composed of patients that had been diagnosed recently.

PIH40

METHODOLOGICAL CONSIDERATIONS WHEN ASSESSING WORK PRODUCTIVITY (WP) AND ACTIVITIES OF DAILY LIVING (ADL) OUTCOMES IN MULTINATIONAL CLINICAL TRIALS IN WOMEN WITH HEAVY AND/OR PROLONGED MENSTRUAL BLEEDING (HPMB) TREATED WITH ESTRADIOL VALERATE/DIENOGEST (E2V/DNG)

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OBJECTIVES: To evaluate the effect of E2V/DNG, an oral contraceptive, on WP (presenteeism) and ADL outcomes in HPMB sufferers using an appropriate analytical strategy. **METHODS:** This was a post-hoc analysis of patient-reported outcomes from two multicenter, randomized, placebo-controlled trials in North America and Europe/Australia that evaluated the efficacy of E2V/DNG in women with HPMB. Data were collected using a modified Work Productivity and Activities Impairment questionnaire. WP and ADL outcomes were measured on a 10-point Likert scale. The analytical strategy was developed to determine and apply the most appropriate statistical methodology given the data and methodological challenges, including highly-skewed, incomplete, multi-country data, unbalanced enrolment across countries, and the auto-regressive nature of the outcomes. The analyses progressed from descriptive statistics to Bayesian regression in several sequential steps. The underlying model chosen for Bayesian analyses was simultaneous equation modeling to incorporate temporal aspects and potential cross-country heterogeneity. **RESULTS:** The data set included 416 patients (E2V/DNG, n = 265; placebo, n = 151) across 12 countries. In all analytical approaches, E2V/DNG vs. placebo treatment showed significantly positive effects on WP and ADL at a magnitude of a one-point change on the Likert scale (based on linear regression analysis). In Bayesian analyses, Gamma distribution yielded a better model fit (DIC = 2129.01 vs. 2460.12 for normal distribution [presenteeism] and DIC = 2313.33 vs. 2640.36 [ADL]). The average treatment effect on presenteeism for Gamma distributed models was −0.82 (95%CI: −1.37, −0.34) at treatment day 84 and −1.06 (95%CI: −1.67, −0.56) at treatment end (EOT; day 196). The average treatment effect on ADL was −1.07 (95%CI: −1.70, −0.52) at day 84 and −1.09 (95%CI: −1.63, −0.62) at EOT. **CONCLUSIONS:** E2V/DNG has a statistically significant and positive impact on presenteeism and ADL impairment. The robustness of these findings was confirmed by the application of several methodological approaches, with Bayesian analyses appropriately dealing with identified methodological challenges.

PIH41

USE OF QUALITATIVE RESEARCH TO IDENTIFY DETERMINANTS OF PERSISTENCE FOR ANTI-OSTEOPOROTIC TREATMENTS

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OBJECTIVES: A large proportion of patients are non-adherent to anti-osteoporotic treatments within 12 months of initiation. In the health psychology literature, several behavioural models have been developed to explain non-adherence, most notably the Health Belief Model (HBM). Based on these, our study aimed to explore determinants of persistence (i.e., continuation) with anti-osteoporotic treatments. **METHODS:** A psychologist carried out face-to-face interviews with patients who had taken anti-osteoporotic treatment for 2 years. Interviews were based on a guide including questions on beliefs and experiences with osteoporosis and its treatment. Saturation was reached with 16 patients providing over 95% of information. Content analysis of interview transcripts was performed to highlight criteria that determine intentions regarding treatment continuation. **RESULTS:** Through patient interview analysis, determinants with an effect on persistence were categorized either as barriers or facilitators. While general health behaviour was identified in both type of determinants, barriers to persistence included: Disease perceived as non-severe ("osteoporosis is not a severe disease, perhaps not a disease at all"); Treatment side-effects ("there are side-effects, I suffer from allergies, I am hesitant to take treatment") and Constraints ("you have to take treatment every day"; "you have to wait 2 hours after dinner before taking treatment"). Facilitators included: Perceived benefits ("my treatment works, bone mineral density results are good"); Habit/maintenance ("I take my treatment because I am used to it, I do not question it") and Relationship with doctor ("I have confidence in my doctor"). **CONCLUSIONS:** Results are consistent with the health psychology models, in particular the HBM. They add new concepts to HBM. Results suggest that areas for improvement in persistence in osteoporosis lay in beliefs about disease and treatment efficacy, rather than treatment convenience.

PIH42

THE USE OF PATIENT-REPORTED OUTCOME MEASURES FOR DRUG APPROVAL IN KOREA

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OBJECTIVES: Patient-Reported Outcomes(PRO) is the information on treatment evaluations that comes directly from a patient. PRO is derived from every endpoint from patient reports. These reports have been recorded in a patient diary or other reporting systems. PRO is an important tool for measuring the impact of diseases, treatments, health and social polices like pharmacoeconomic polices. The objective of this study is to determine the level and nature of the use of PRO compared to other endpoints for Korea's approved new drugs. **METHODS:** A survey has been conducted for 121 newly approved products in Korea during the period of 2005 to 2009. Different survey forms were prepared for each product. Each survey form provided information on products and clinical trials: title, objectives, types of endpoints, types of PRO and the information on PRO sent by e-mail to the manager of each pharmaceutical company. **RESULTS:** Primary endpoints were measured in 200 clinical trials whereas secondary endpoints were measured in 183 clinical trials. The two both studied 111 products. For PRO, a primary endpoint was reported in 33(14.6%) trials and a secondary has been reported in 66(25.1%) trials. For Clinician-reported outcomes, the figures were 104(46.0%) and 108(41.1%), respectively. For Laboratory/device endpoints, the figures were 89(39%) and 89(33.7%), respectively. For 11 products, PROs have been used as the only type of endpoint. About 40 percent of PROs have been used as primary and secondary endpoints in clinical trials for drug approval during the last five years(2005~2009). However, the results of the PRO secondary endpoints have not been reflected in product labeling. **CONCLUSIONS:** PRO has been used as a useful endpoint that can be employed in clinical trials for the development and evaluation of new drugs. Therefore, it is necessary to develop PRO instruments and guidelines to evaluate Korean patients' PRO for Koreans and clinical trials at home.